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09/892,900

Filed

: June 26, 2001

REMARKS

In response to the Office Action mailed January 30, 2003, Applicant respectfully requests the Examiner to reconsider the above-captioned application in view of the foregoing amendments and the following comments. As a result of the amendments listed above, Claims 14-17, 19, 23 and 24 remain pending, Claims 18, 20-22 and 25-27 being withdrawn as being directed to a non-elected species. Claim 23 has been amended.

In the changes made by the current amendment, deletions are shown by strikethrough, and additions are underlined.

Applicants Request Reinstatement Of Claims 20-22 and 25-27

In the outstanding Office Action, the Examiner has withdrawn Claims 18, 20-22 and 25-27 as being directed to a non-elected species. In the Response to Election of Species Requirement filed November 1, 2002, Applicants indicated that Claims 14-17 and 19-27 read on the elected species of Figures 52-55. Applicants respectfully submit that only Claim 18 should be withdrawn and request that Claims 20-22 and 25-27 be reinstated for prosecution.

Each of Claims 20-22 and 25-27 recite a first spring and a second spring, i.e., two springs, and a parallelogram linkage assembly. However, the parallelogram linkage assembly, in itself, does not necessarily include spring members. As recited in the relevant claims, the first and second springs operate in conjunction with the parallelogram assembly. Therefore, Claims 20-22 and 25-27 do not require at least <u>four</u> springs, as suggested by the Examiner. Accordingly, Applicants respectfully request reinstatement of Claims 20-22 and 25-27.

The Priority Claim Has Been Corrected

The priority claim as amended in the preliminary amendment filed June 26, 2001 inadvertently omitted the grandparent application, U.S. Patent Application No. 08/008,790, filed January 22, 1993. The priority claim has been corrected by the present amendment. Accordingly, the earliest effective filing date of the present application is January 24, 1992, the filing date of Application No. 07/824, 855, which issued as U.S. Patent No. 5,911,716. In addition, the priority claim has been amended to indicate that the present application is a divisional, rather than a continuation, of Application No. 08/876,180, as suggested by the Examiner in paragraph 5 of the outstanding Office Action.

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The Title Has Been Amended

The Examiner has objected to the Title as not being descriptive of the claimed invention. In response, Applicants have amended the title to "PLATEN PUMP". Applicants respectfully submit that the amended title is descriptive of the claimed invention and request withdrawal of the present objection.

The Abstract Has Been Amended To Comply With M.P.E.P. §608.01(b)

The Abstract is objected to for containing terminology which can be inferred. Applicants have amended the Abstract to delete such terminology. Specifically, the Abstract has been amended to delete the term "Disclosed is" from the first sentence. Accordingly, Applicants respectfully submit that the Abstract now complies with M.P.E.P. §608.01(b) and request withdrawal of the present objection.

The Drawings Have Been Amended To Overcome The Outstanding Objections

The drawings presently stand objected to because of a number of informalities. In response, Applicants have amended the drawings to address each of the informalities noted by the Examiner in the outstanding Office Action. The changes to the individual Figures are set forth below. Replacement drawings incorporating these changes are filed herewith.

Figure 4 has been amended so that the lead line from reference numeral 23 clearly indicates the spring stop, as described on page 11, line 20 of the specification.

Figure 8a has been amended so that the lead line from the reference numeral 124 clearly indicates the platen.

Figure 8b has been amended so that the lead lines from reference numerals 114 and 117 indicate the spring and chamber, respectively.

Figure 10 has been amended so that the lead line from the reference numeral 186 clearly indicates the flange of the first platen segment 176.

Figure 16 has been amended to delete the reference numeral 216 and the associated lead line.

Figure 25 has been amended so that the lead line from the reference numeral 263 clearly indicates the flange of the first segment 260 of the collapsible retractor 258.

Figure 34 has been amended to add the label 35-35 to the existing view line.

Figure 36 has been amended to add the label 37-37 to the existing view line.

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Figure 39 has been amended to add reference numeral 318 to indicate the base, as described on page 35, lines 32 through 34 of the present specification.

Figure 46 has been amended to add the label 47-47 to the existing straight view line and the label 46A to the existing circular view line.

Figure 48 has been amended to change the lead line for reference numeral 364 into a dashed line.

Figure 49 has been amended to change the lead lines for reference numerals 364 and 366 into dashed lines.

Figure 50 has been amended to change the lead line for reference numeral 368 into a dashed line. In addition, Figure 50 has been amended to replace previous reference numeral 370 with reference numeral 372 to indicate the left slot and add new reference numeral 370 to indicate the right slot.

Figure 51 has been amended to add reference numeral 368 to indicate the fluid medication bag, as described on page 42, lines 11 through 16 of the present specification. In addition, Figure 51 has been amended to replace previous reference numeral 370 with reference numeral 370 to indicate the left slot and add new reference numeral 370 to indicate the right slot.

Figure 52 has been amended to change the lead line for reference numeral 411 into a dashed line. In addition, Figure 52 has been amended to add the label 53-53 to the existing view line.

Figure 53 has been amended to change the lead line for reference numeral 438 into a dashed line. Figure 53 has also been amended so that the lead lines from the reference numerals 412 and 412' clearly indicate the left and right springs, respectively, and the lead line from reference numeral 421 clearly indicates the aperture of the nut 416.

Figure 54 has been amended to change the lead line for reference numeral 438 into a dashed line. Figure 54 has also been amended so that the lead line from reference numeral 421 clearly indicates the aperture of the nut 416. In addition, Figure 54 has been amended to clearly illustrate the level indicator 451, as described on page 51, lines 18 through 21 of the present specification.

Figures 56-60 have been amended to include proper labeling of the axes of each graph. Support for the labels are provided at least by page 7, lines 26-32; page 53, line 30 through page 754, line 24; and page 29, lines 3 through 8 of the present specification.

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Figures 66-69 have been amended to add the reference numeral 572 to indicate the seam of the medication bag 560.

The Specification Has Been Amended To Correct Informalities Noted By The Examiner

The specification is objected to because of a number of informalities set forth in Paragraph 11 of the outstanding Office Action. Applicants have made a good faith effort to respond to each objection by the amendments to the specification and drawings above. With respect to item 8, Applicants respectfully submit that the description on page 24, lines 7-9 and Figures 18-20 are consistent. Figures 18 and 20 clearly illustrate the lever 220 extending *slightly* beyond an outer periphery of the housing 232, as described on page 24, lines 7-9. Accordingly, no amendment has been made to either Figures 18-20 or the description on page 24, lines 7-9.

Due to the amendments to the specification and drawings above and the comments of the preceding paragraph, Applicants respectfully submit that each of the objections of Paragraph 11 of the outstanding Office Action have been addressed. Accordingly, Applicants respectfully request reconsideration and withdrawal of the present objection to the specification.

Claims 23 And 24 Comply With 35 U.S.C. § 112, Second Paragraph

Claims 23 and 24 presently stand rejected under 35 U.S.C. § 112, second paragraph as being indefinite. Claim 23 has been amended to correct antecedent basis. Specifically, "said at least one spring" in the last paragraph of the claim has been amended to recite "at least one spring". Accordingly, Applicants respectfully submit that, as amended, Claim 23 now complies with 35 U.S.C. § 112, second paragraph. Furthermore, as a result of the amendment of Claim 23, dependent Claim 24 now also complies with 35 U.S.C. § 112, second paragraph. Withdrawal of the present rejection of Claims 23 and 24 is respectfully requested.

Rake et al. Is Not Prior Art To The Present Application

Claims 14-17, 19 and 23-24 presently stand rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 5,911,716 to Rake et al. Applicants respectfully submit that Rake et al. is not prior art to the present application and request reconsideration and withdrawal of the present rejection.

As set forth above, the priority claim as submitted in the preliminary amendment filed June 26, 2001 inadvertently omitted the grandparent to the present application. The priority claim has been amended herein to include the grandparent application and, as a result, the

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effective filing date of the present application is the same as the filing date of Rake et al., i.e., January 24, 1992.

Therefore, Rake et al. is not prior art to the present application under 35 U.S.C. § 102(e). Accordingly, Applicants respectfully request reconsideration and withdrawal of the present rejection of Claims 14-17, 19 and 23-24 in light of Rake et al.

Bessesen Does Not Anticipate Claims 14-17, 19 and 23

Claims 14-17, 19 and 23 presently stand rejected under 35 U.S.C. § 102(b) as being anticipated by Bessesen. Applicants respectfully submit that the Bessesen reference does not anticipate Claims 14-17, 19 and 23 and request reconsideration and withdrawal of the present rejection.

The Bessesen reference discloses a syringe including a spring-biased piston (15) that is configured to apply a pressure to a fluid within a reservoir defined by a barrel (1) of the syringe. The surface of the piston that faces the fluid reservoir is hemispherical in shape. An end surface of the barrel opposing the hemispherical surface of the piston is conical in shape. Thus, if the piston is in a position minimizing the volume of the reservoir, the hemispherical surface of the piston and the conical surface of the barrel would contact one another only along a contact radius positioned between a central axis of the reservoir and an outer circumference of the reservoir.

Such a construction results in a residual amount of fluid being retained within the reservoir when the piston is fully extended into the reservoir. A first amount of fluid would be retained within an area defined within the contact radius between the piston and the barrel and a second amount of fluid would be retained within an annular area outside of the contact radius. While retained fluid may be acceptable in a syringe, it would be highly undesirable in an infusion pump due, at least in part, to the significantly larger volume of fluid typically dispensed from an infusion pump versus the volume dispensed from a syringe. In addition, in the context of an infusion pump, retained fluid within the reservoir would decrease the length of the infusion cycle, or require a larger reservoir to compensate for the retained volume of fluid. Either condition would be highly undesirable in an infusion pump application.

In contrast, Claim 14 recites an infusion pump including, among other limitations, a first shell defining a non-planar interior surface and a platen defining a non-planar surface complementary to the surface of the first shell. The surfaces of the first shell and the platen are

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configured to receive a fluid delivery bag therebetween. The platen is biased to compress the fluid delivery bag between the surfaces of the first shell and platen.

Such a construction, as described in the present specification, advantageously permits the infusion pump to substantially completely deliver the fluid within the fluid delivery bag. See page 14, lines 9-24 for example. Thus, with complementary surface configurations, the length of the fluid delivery cycle is optimized and waste of medicinal fluid is minimized. Furthermore, one of skill in the art would recognize that to be complementary, the surfaces of the platen and the first shell require greater conformance between their shapes than that necessary to produce a simple contact radius, or circular line of contact, as would occur in the construction of the Bessesen reference. Accordingly, Applicants respectfully submit that the Bessesen reference does not disclose the necessary "complementary" surfaces to anticipate Claim 14.

In addition, it is respectfully submitted that piston (15) of the Bessesen reference does not anticipate the platen limitation of Claim 14 either. A platen is a plate-like member. As discussed in the present specification, the provision of a platen defining a surface for compressing the fluid delivery bag permits a relative constant contact area between the platen and the bag during the fluid delivery cycle. If the platen were replaced with a hemispherical piston of the Bessesen reference, the contact area between the piston and a fluid delivery bag would sharply increase over the initial portion of the fluid delivery cycle.

For at least the reasons presented above, Applicants respectfully submit that Claim 14 is not anticipated by the Bessesen reference. Independent Claims 19 and 23 include limitations similar to the limitations of Claim 14 discussed above and are allowable at least for essentially the same reasons. The remaining dependent claims are allowable, not only because they depend from allowable independent claims, but on their own merit as well. Accordingly, Applicants respectfully request reconsideration and withdrawal of the present rejection of Claims 14-17, 19 and 23.

Claims 14-15, 17, 19 and 23-24 Are Patentable Over The Applied Combination Of May/Dorman/Jassawalla et al.

Claims 14-15, 17, 19 and 23-24 presently stand rejected under 35 U.S.C. § 103(a) as being unpatentable over May in view of Dorman et al. and <u>Jassawalla et al.</u>. Applicants respectfully submit that Claims 14-15, 17, 19 and 23-24 are patentable over the applied combination and request reconsideration and withdrawal of the present rejection.

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The May reference discloses a combined wound irrigator and evacuator device. The device of May includes a housing having an interior space divided into an irrigator section and an evacuator section by a diaphragm or, alternatively, by a piston. The volumes of the irrigator section and the evacuator section are inversely affected by movement of the diaphragm (or piston). That is, in operation, the diaphragm is biased to reduce a volume of the irrigator section to expel an irrigation fluid therefrom while the volume of the evacuator section is increased to draw fluid from the wound into the evacuator section. The May reference does not, however, disclose non-planar complementary surfaces acting to compress a fluid delivery bag.

The Examiner states that it would be obvious to one of skill in the art to combine the combined irrigator/evacuator of the May reference with the infusion pump constructions of the Dorman et al. and Jassawalla et al. references to arrive at the constructions recited in Claims 14-15, 17, 19 and 23-24. The Dorman et al. reference discloses an infusion pump utilizing a plurality of diaphragm springs to provide a biasing force to expel fluid from the pump. The Jassawalla et al. reference discloses an infusion pump including a motor-driven, collapsible bellows arrangement to expel fluid from the pump. Each of the Dorman et al. and Jassawalla et al. references disclose infusion pumps with opposing non-planar surfaces that are similar in shape to one another.

Applicants respectfully submit that any motivation for combining these references, as suggested by the Examiner, is the result of hindsight resulting from the teaching of the present application. The Examiner states that a motivation to combine the references results from the recognition of that the constructions of the Dorman et al. and Jassawalla et al. references would provide more complete expelling of fluid and the desire of the May reference to cost efficiently expel fluids. As an initial matter, however, it does not appear that the expulsion of fluid from the combined irrigator/evacuator disclosed in the May reference would be less than complete and the specification of the May reference does not provide any indication to the contrary. Both embodiments disclosed in the May reference include flat opposing surfaces for compressing the fluid bag therebetween and there is no indication that the opposing surfaces would be prevented from completely compressing the fluid bag. Thus, no motivation exists to modify the May reference with features of either the Dorman et al. or Jassawalla et al. references under the motivation stated by the Examiner.

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In addition, the non-planar surface of the bottom wall (26) of the infusion pump disclosed in the Dorman et al. reference is necessitated due to the inclusion of multiple diaphragm springs within the wall. The similar shape of the opposing surface is provided to permit substantially complete expulsion of fluid from the infusion pump of Dorman et al. However, no motivation is provided to modify the flat surfaces of the combined irrigator/evacuator disclosed in the May reference absent the inclusion of diaphragm springs.

The conical surfaces of the infusion pump disclosed in the Jassawalla et al. reference are provided so that any air bubbles within the reservoir (14) may be easily evacuated. The fluid exit passage (25) opens into the center of the reservoir so that when the device is orientated as shown in Figure 2, the passage is at the highest point of the reservoir. Accordingly, air bubbles are evacuated from the reservoir to prevent air from being introduced into a patient. In the combined irrigator/evacuator disclosed in the May reference, the irrigation fluid is contained within a fluid bag. Presumably, air would be evacuated from the fluid bag during the process of filling the fluid bag with irrigation fluid. Thus, no motivation would exist to modify the combined irrigator/evacuator of the May reference to include non-planar surfaces similar to those of the Jassawalla et al. reference.

For at least the reasons presented above, Applicants respectfully submit that the applied combination of May/Dorman et al./Jassawalla et al. is improper. Thus, Applicants respectfully request reconsideration and withdrawal of the present rejection of Claims 14-15, 17, 19 and 23-24.

Double Patenting Rejection In View Of Rake et al. Is Inapplicable To The Present Application

As presented above, the priority claim in the present application has been amended such that the present application claims priority to the filing date of the Rake et al. application. Thus, as set forth in 35 U.S.C. § 121, the Rake et al. patent shall not be used as a reference against the present application. Accordingly, Applicants respectfully request reconsideration and withdrawal of the present rejection.

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CONCLUSION

For the foregoing reasons, it is respectfully submitted that the rejections set forth in the outstanding Office Action are inapplicable to the present claims and specification. Accordingly, early issuance of a Notice of Allowance is most earnestly solicited.

The undersigned has made a good faith effort to respond to all of the rejections in the case and to place the claims in condition for immediate allowance. Nevertheless, if any undeveloped issues remain or if any issues require clarification, the Examiner is respectfully requested to call Applicant's attorney at the number provided below, to resolve such issue promptly.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: JULY 29, 2003

By: Curtiss C. Dosier

Registration No. 46,670

Attorney of Record

Customer No. 20,995

(949) 760-0404

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